



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service

HFI-35

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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

WARNING LETTER

FLA-97-73

July 25, 1997

Mr. Eric J. Jolly
Chief Executive Officer
Hyperion Medical, Inc.
4203 Vineland Rd. #K-14
Orlando, Florida 32811

Dear Mr. Jolly:

We are writing you because on July 10, and July 15 through 17, 1997 FDA Investigator R. Kevin Vogel collected information that revealed serious regulatory problems involving Hydrophilic Wound Gel and Hydrophilic Wound Dressing products for which your firm acts as the specification developer and which are marketed by your firm.

Under the Federal Food, Drug and Cosmetic Act (the Act), these products are considered to be medical devices because they are used to treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices conform with the Current Good Manufacturing Practice (CGMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that your devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacture, packing, storage, or installation are not in conformance with the CGMP. These violations include, but are not limited to the following:

- Failure to assure that medical devices which are labeled and marketed as sterile are adequately sterilized since sterilization validation has not been conducted, e.g., bioburden and the Sterility Assurance Level (SAL) has not been determined without preservatives being added prior to the sterilization cycle.
- Firm's written agreements covering interstate shipment of its medical devices (which are labeled sterile) to their contract sterilizer fail to state in detail the sterilization process including definition and assignment

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of responsibility for validation of sterilization, communication about changes, audit privileges, documentation, and product release.

- Failure to have a Quality Assurance Audit procedure including audit schedule and audit criteria.
- Purchasing control procedures are inadequate, e.g.:
 - a) Failure to have and maintain documentation of audit schedules for contract manufacturers and appropriate criteria covered during audits,
 - b) Failure to specify and inspect each contract manufacturer for conformance to all acceptance criteria, e.g., no testing of concentration of preservative ingredients in Wound Gel and Dressing devices, and
 - c) Failure to assure sampling plan is based on a valid, statistical rationale.

You should know that these are serious violations of the law that may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please let this office know in writing within (15) working days from the date you receive this letter what steps you are taking to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, Florida District, 7200 Lake Ellenor Dr., Suite #120, Orlando, Florida 32809.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the requirements for conformance of your devices with the GMPs and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1- (800) 638-2041 or through the Internet at <http://www.fda.gov>.

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If you have more specific questions about the GMP requirements and how they affect your particular device, or about the content of this letter, please contact Tim Couzins at (407) 648-6823, ext. #264.

Sincerely,

A handwritten signature in cursive script, reading "Douglas D. Tolen". The signature is written in dark ink and is positioned above the printed name and title.

Douglas D. Tolen
Director, Florida District